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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: 37697-0039

Applicant(s): William H. HARRIS *et al.*

Confirmation No.: 8865

Serial No.: 10/040,900

Examiner: Paul B. Prebilic

Filing Date: January 9, 2002

Group Art Unit: 3738

Title: POLYETHYLENE HIP JOINT PROSTHESIS WITH EXTENDED
RANGE OF MOTION

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450


Sir:

Applicants submit herewith the original Declaration of Dr. William H. Harris dated February 17, 2005. A facsimile copy of the Declaration was filed in the USPTO on February 22, 2005, however, the copy was not completely legible.

Respectfully submitted,

March 29, 2005
Date

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DECLARATION OF DR. WILLIAM H. HARRIS

I, William H. Harris, do hereby declare as follows:

1. I understand that the claims in the captioned application have been rejected over Graham *et al.* (US 5,549,700) or Townley *et al.* (US 6,096,084) in view of McKellop *et al.* ("McKellop", US 6,165,220). In order to address this rejection, I submitted a declaration, filed on July 6, 2004. It appeared to me that the Examiner has understood my declaration suggesting a "trend in the art to smaller diameter surfaces", but the examiner has not addressed the "disadvantages of using larger diameter surfaces", which were made of conventional UHMWPE, such as used by Towley.

2. It appears that the Examiner has misunderstood my previous declaration, and therefore a clarification would be useful in considering (i) the content of the prior art, especially, regarding linear versus volumetric wear, and (ii) that the invention has satisfied a long felt unmet need in the field.

3. Regarding Exhibit I (Elfeck *et al.*, 1998) of my July 6, 2004 declaration, the Examiner quoted that there is "no actual proof" provided in the Exhibit that larger head sizes resulted in higher wear rate. Elfeck *et al.* (Tab-1) reported that "[a] 32-mm-diameter head has a 45% greater sliding distance than a 22-mm head per cycle; hence as wear is proportional to sliding distance, the wear should be 45% larger per cycle." (see page 294, first column, last paragraph). Elfeck *et al.* further stated that "[the] most important conclusion to be drawn from this study is the detrimental effect of the large

femoral head size. This accelerates the volumetric wear rate, therefore reducing the components' expected life. An additional consequence of the 32-mm head is the reduction in polyethylene thickness attainable for a given acetabular outer diameter." (see "Conclusion" on page 295, first paragraph). Thus, Elfeck *et al.* provided sufficient proof that larger head sizes resulted in higher wear rate.

4. Regarding Exhibit II (Livermore *et al.*, 1990) of my July 6, 2004 declaration, the Examiner quoted that the "difference in wear between 28 mm and 32 mm diameter surfaces [] were not statistically significant." The Examiner has not addressed the difference between the liner wear rate and the volumetric wear rate. The phrase "difference in wear between 28 and 32 mm surfaces were not statistically significant" refers to the linear penetration, not to the volumetric wear. Because the diameter of the 32 mm head exceeds that of the 28 mm head, the greatest volumetric wear and mean wear rate (in contrast with linear penetration rate) were greater for the 32 mm heads than the 28 mm heads. Volumetric wear is the key, not linear penetration. See Livermore *et al.* (1990) (Tab-2), for example, page 523, Table I, which shows head sizes of 22 mm, 28 mm, and 32 mm generated 1.35 mm, 0.85 mm, and 1.10 mm linear wear, respectively. Whereas, the volumetric wear for the head sizes 22 mm, 28 mm, and 32 mm were 513 mm³, 521 mm³, and 911 mm³, respectively. In short, 32 mm heads generated far greater volumetric wear than 22 mm and 28 mm heads against conventional polyethylene.

5. The critical issue as far the failure of total hip replacements concerned is the volumetric wear. Volumetric wear is responsible for the total number of particles generated that elicits the adverse biological response that leads to the bone resorption (periprosthetic osteolysis). It is the periprosthetic osteolysis or bone resorption that causes re-operations and leads to loss of fixation of the components. Thus, it is clear that larger heads in the ranges used at the time generated greater volumetric wear, and thereby generated more particles. Data are recorded in the exhibits submitted earlier, see for example:

Schmalzried *et al.* (1999) (Tab-3) demonstrated that "[t]he large diameter of these components [referring to surface replacement] results in a volumetric wear of

polyethylene that is 4-10 times higher than that produced by a conventional 28 mm diameter bearing for the equivalent number of cycles." (See page 148, Fig. 1 legend).

Clarke *et al.* (1997) (Tab-4) also reported an increase in volumetric wear rate with increase in head size. See for example, page 30, Table 4, which shows a range of 23.2 mm³ to 32.8 mm³ volumetric wear rate for head sizes ranging from 22.25 mm to 28 mm, respectively. Clarke *et al.* summarized that the "[v]olumetric wear rate increased with respect to size of femoral head and a linearly increasing relationship of 7-8 per cent/mm was evident with respect to femoral head diameter for both PTFE and polyethylene." (see page 25, Abstract).

6. When larger head diameters (i.e., larger than 32 mm) are used against conventional polyethylene, the wear rate is even greater. This is illustrated convincingly and importantly by the long term report of the outcomes of the total articular replacement arthroplasty (TARA) prosthesis (see Treuting *et al.*, Prohibitive failure rate of the total articular replacement arthroplasty of 5-10 years. *American Journal of Orthopedics*, 1997:114-118, Tab-5). Treuting *et al.* used "acetabular component sizes ranged from 56 mm to 62 mm in outer diameter, while femoral component sizes ranged from 45 mm to 55 mm in head diameter" (see for example, page 114, second column, under "Materials and Methods") and reported an "overall clinical failure rate [of] 89% (55/62 hips)" (see for example, page 115, right column, under "Results"). Treuting *et al.* conclude that the "factors associated with increased polyethylene wear" include "large diameter of the bearing", and state that "the volumetric wear rate of hip resurfacing components is 4-10 times higher than that of a conventional 28-mm hip bearing." (see page 117, right column last paragraph).

7. Regarding Exhibit IV (Hirakawa *et al.* 1997) of my July 6, 2004 declaration, the Examiner has alleged that there is "provided no actual data." Please note that Exhibit IV informed the field that "higher wear rate" occurred, and thus summarized data and results of the study that is responsible for the knowledge of the field. Data in a descriptive format or in a tabular data format represents the same finding, and thus illustrates the view of the field at the time.

Hirakawa *et al.* studied the relationship between three different femoral head sizes (26, 28, and 32 mm) and the characteristics of wear debris in the adjacent tissues. Hirakawa *et al.* reported that the "[l]arge femoral head diameter (32 mm) was found to correlate significantly with large particle size (diameter and surface area, $p < 0.05$), high tissue concentration of particles (particle volume/gram of tissue, $p < 0.01$), and high rate of particle production (particles volume/month, $p < 0.05$)." The quantitative assays conducted by Hirakawa *et al.* reconfirms that "higher volumetric wear [is] associated with 32 mm femoral head components."

8. There was a direct relationship between the volume of wear produced and the size of the head. Large heads produce a greater volume of wear. As submitted with my previous declaration, Charnley, who invented total hip replacement surgery, was forced to go to smaller and smaller head sizes despite the fact that his original proposed head size was 45 mm in diameter. Charnley was forced to do this because he found that the wear for the larger head sizes was excessive. This is well documented in his book (John Charnley, 1979, *Low Friction Arthroplasty of the Hip: Theory and Practice*, Springer-Verlag, Berlin, Heidelberg, New York, 1979. Pages 3-15, (Tab-6)). See for example, Charnley describes "loading of a small-diameter ball can prevent 'third body' abrasion" (on page 6, right column, last paragraph), "small-diameter femoral head demanded by the theory of low frictional torque" (on page 13, left column, first paragraph), "general trend [] for designs of metal-to-plastic total hip to be moving towards the smaller ranges of femoral head (32, 28 and 25 mm)" (on page 14, right column, first paragraph).

In sum, Charnley experienced the fact that large heads produce a greater volume of wear when he introduced Teflon type plastics. Charnley also observed this wear when switched to the conventional UHMWPE. The observation has subsequently been confirmed by a wide number of studies. For example, Livermore, *et al.* (Tab-2) disclose that "[t]he greatest volumetric wear and mean rate of volumetric wear were seen with thirty-two-millimeter components", who studied the effect of femoral head size on wear of acetabular component made of conventional polyethylene (See page 518, Abstract).

9. In summary, the two dominant observations from the above publications are: (i) increasing head size increases the volumetric wear, which leads to adverse biological consequences; and (ii) an even greater increase in the wear rate occurs if the femoral head is greater than 32 mm in diameter. The art cited by the Examiner shows that prior art approaches with large head diameters were failure, which is reinforced by McKellop's exclusive focus on heads having diameter of less than 32 mm. Therefore, McKellop teaches away from using large head sizes. Hence, there is no motivation in McKellop to use its cross-linked materials for large head prosthesis, such as those greater than 32 mm.

10. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

2/17/05
Date

William H. Harris
William H. Harris